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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,239	10/27/2000	Marie-Pascale Doutriaux	A33153-PCT USA	1839

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EXAMINER

KRUSE, DAVID H

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 04/09/2003

27

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Offic Action Summary	Application No.	Applicant(s)
	09/529,239	DOUTRIAUX ET AL.
	Examiner David H Kruse	Art Unit 1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 26 September 2002 and 17 January 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 3,8-10,12-23,29,30,32,33 and 37-44 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 38-44 is/are allowed.
- 6) Claim(s) 3,8-10,12-23,29,30,32,33 and 37 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 17.
- 4) Interview Summary (PTO-413) Paper No(s) _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

1. This Office action is in response to the Amendment and Remarks filed 26 September 2002 and the response filed 17 January 2003.
2. The application is now in compliance with the Sequence Rules.
3. The Information Disclosure Statement filed 30 September 2002, with the PTO-1449 form, has been considered, a signed copy is attached hereto.
4. Those rejections and objections not specifically addressed in this Office action are withdrawn in view of Applicant's amendments and/or remarks filed 26 September 2002.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
6. The drawings in this application are objected to by the Draftsperson as informal. See the attached copy of PTO-948 form, original attached to Paper No. 16, mailed 21 May 2002. Applicant is reminded that correction of the drawings cannot be held in abeyance, and that formal drawings are required in response to this Office Action as outlined in 37 CFR § 1.85(a). Failure to take corrective action within the set period will be considered non-responsive to this Office action.

Claim Objections

7. Claim 17 is objected to because of the following informalities: Said claim is missing an article of language and should read -- A plasmid --. Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. Claims 3, 8-10, 12-23, 29, 30, 32 and 33 remain rejected and claim 37 is rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 21 May 2002. Applicant's arguments filed 26 September 2002 have been fully considered but they are not persuasive.

Applicant argues that the artisan of ordinary skill would recognize that Applicants had possession of at least nucleic acids within the scope of claim 37 at the time the application was filed in view of SEQ ID NOS: 18 and 19 [nucleotide sequence and the encoded polypeptide sequence respectively]. Applicant argues that the artisan of ordinary skill would recognize that Applicants had possession of nucleic acids within the scope of claims 3 and 38, and that at claim 13 the functional limitations do not constitute the sole definition of the claimed nucleic acids (page 18, 2nd paragraph of the Remarks). This argument is not found to be persuasive because Applicant has only described one nucleotide sequence that encodes an *Arabidopsis thaliana* AtMSH3 protein and does not adequately describe the genus of isolated and purified nucleic acids encoding a polypeptide having an amino acid sequence at least 50% identical to SEQ ID NO: 19, even from other plants, by which one of skill in the art would recognize that Applicant was in possession of such a genus of nucleic acids. In addition, Applicant does not describe the genus of nucleic acids having at least 50% identity to SEQ ID NO: 18 as

required to make the chimeric gene at claims 13-16, to make the plasmid of claim 17, to make the plants of claims 18-20, or to practice the processes of claims 22-30, 32 and 33. See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997), which teaches that a cDNA is not defined or described by the mere name "cDNA", even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA, and that a description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. In the instant case, Applicant only describes one species of nucleic acid encoding a plant MSH3, in addition Applicant only describes structural features known to one of skill in the art at the time of the invention that are common to MSH3 proteins, not structural features that are common to the members of the claimed genus *per se*, by which one of skill in the art could recognize the claimed genus of 50% identical to SEQ ID NO: 19 (see Figure 5).

See also, MPEP § 2163 which states that the claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the

sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

9. Claims 3, 8-10, 12-23, 29, 30, 32 and 33 remain rejected and claim 37 is rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for an isolated and purified nucleic acid that encodes a polypeptide having the sequence of SEQ ID NO: 19, compositions comprising said isolated and purified nucleic acid and methods of using said isolated and purified nucleic acid in a transformed plant, does not reasonably provide enablement for an isolated and purified nucleic acid that encodes a polypeptide that is at least 50% identical to the amino acid sequence of SEQ ID NO: 19, or compositions comprising said isolated and purified nucleic acid or methods of use. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection is repeated for the reason of record as set forth in the last Office action mailed 21 May 2002. Applicant's arguments filed 26 September 2002 have been fully considered but they are not persuasive.

Applicant argues that one of ordinary skill in the art would recognize that plant mismatch repair proteins are highly conserved. Applicant cites the teachings of Cao *et al* 2000, Xu *et al* 1998, and Tuteja *et al* 2001. Applicant argues that the high degree of conservation of mismatch repair proteins, the guidance provided in the instant specification together with the 50 % identity recitation of the claims is sufficient to allow the artisan of ordinary skill to recognize all nucleic acids within the scope of the claims (paragraph spanning pages 19-20 of the Remarks). This argument is not found to be

persuasive because Applicant has only taught a single species of plant MSH3 polypeptide in the instant application as discussed above. In addition, the teachings in the art to which Applicant refers, Cao, Xu and Tuteja each teach that the conservation is in the function of the proteins involved in mismatch repair and are silent as to the conservation of the structure of the plant proteins involved in mismatch repair.

Applicant argues that the literature is replete with examples of effective use of antisense technology to regulate target gene expression in plants (page 20, 3rd paragraph of the Remarks). The Examiner does not contest the assertion that antisense technology to regulate target gene expression in plants is well established, the Examiner asserts that use of heterologous antisense constructs to regulate target gene expression in heterologous plants is unpredictable and would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to practice the invention as broadly claimed. Reference No. 18, Kalkenhoff et al 1998, The Plant Journal 14(1): 121-128, to which Applicant refers as disclosing effective, predictable use of antisense technology to regulate DNA repair genes, in fact teaches regulating expression of aquaporin PIP1b using a homologous antisense construct in the homologous plant, and that expression of PIP1a was also regulated by the antisense construct, speculating that because PIP1b and PIP1a have 83% nucleotide sequence identity, that cross regulation occurs but that PIP1c and PIP2b were not affected because they had 76% and 66% nucleotide sequence identity respectively (see page 125, left column, last paragraph).

Applicant argues that while the art cited in the IDS filed 30 September 2002 (references filed 26 September 2002) may not demonstrate absolute predictability, it clearly establishes that a substantial degree of predictability exists (paragraph spanning pages 20-21 of the Remarks). The Examiner has reviewed the supplied references and responds that the art teaches that use of homologous antisense constructs to regulate expression of homologous genes in homologous plants is, for the most part, a predictable art. The Examiner takes exception to Applicant's assertion that the use of antisense constructs to regulate gene expression is predictable when one of skill in the art attempts to regulate a heterologous gene's expression with a heterologous antisense construct, without undue trial and error experimentation.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. The claims are free of the prior art which neither teaches nor fairly suggests a nucleic acid that is at least 50% identical to SEQ ID NO: 18 or that encodes a polypeptide that is at least 50% identical to SEQ ID NO: 19, compositions comprising said nucleic acid or method of using said nucleic acid.

12. Claims 38-44 are allowed.

13. Claims 3, 8-10, 12-23, 29, 30, 32 and 33 remain rejected and claim 37 is rejected.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

David H. Kruse, Ph.D.
31 March 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180 1638

